

What is claimed is:

1. A method of diagnosing bladder cancer in a subject which

5 *Sub C*) comprises the step of:

10 determining, in a sample from the subject, the level of expression of at least one polypeptide -encoding polynucleotide, wherein a higher level of expression of the polynucleotide compared to the level of expression of the polynucleotide in a subject free of bladder cancer is indicative of bladder cancer, and wherein the polypeptide -encoding polynucleotide comprises a polynucleotide selected from the group consisting of essentially of

15 (a) the polynucleotides listed in Tables 3, 4 and 6;

20 (b) polynucleotides having sequences that differ from the polynucleotides in (a), without changing the polypeptide encoded thereby; and

25 (c) polynucleotides which are at least 70% homologous to the polynucleotides of (a).

30 2. The method according to claim 1, wherein said determining

35 step includes determining the level of expression of at least one polypeptide -encoding polynucleotide, wherein the polypeptide -encoding polynucleotide comprises a polynucleotide selected from the group consisting of the polynucleotides listed in Tables 3, 4 and 6.

3 The method according to claim 2, wherein said determining step includes determining the level of expression of at least one polypeptide – encoding polynucleotide, wherein the polypeptide –encoding polynucleotide comprises a polynucleotide selected from the group consisting of the polynucleotides listed in Table 6.

10 *SubC2* 4 The method according to claim 1, wherein the analyzing step includes the step of using mRNA from the expressed gene to hybridize to at least one of the sequences in Tables 3, 4 and 6.

15 5. The method according to claim 1, wherein the analyzing step includes the step of using RT-PCR technology.

20 6. The method according to claim 1, wherein the analyzing step includes the step of using a specific antibody to detect the presence of a polypeptide encoded by said polynucleotide.

25 *SubC3* 7. A method of diagnosis of stageTa in transitional cell carcinoma which comprises the step of: determining, in a sample from the patient, the level of expression of 30 at least one polypeptide –encoding polynucleotide, wherein a higher level of expression of the polynucleotide compared to the level of expression of the polynucleotide in a patient free of transitional cell carcinoma is indicative of 35 stageTa , and wherein the polypeptide –encoding polynucleotide is selected from a polynucleotide selected from the group consisting of

40 (a) the polynucleotides listed in Tables 3, 4 and 6;

Sub C3

(b) polynucleotides having sequences that differ from the polynucleotides in (a), without changing the polypeptide encoded thereby; and

(c) polynucleotides which are at least 70% homologous to the polynucleotides of (a).

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8. The method according to claim 7 wherein said determining step includes determining the level of expression of at least one polypeptide – encoding polynucleotide, wherein the polypeptide –encoding polynucleotide encodes Keratin 13.

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Sub C4

9. A method of differential diagnosis of stageT1 in transitional cell carcinoma which comprises the step of:

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determining, in a sample from the patient, the level of expression of at least one polypeptide –encoding polynucleotide, wherein a higher level of expression of the polynucleotide compared to the level of expression of the polynucleotide in a patient free of transitional cell carcinoma is indicative of stageT1, and wherein the polypeptide –encoding polynucleotide comprises a polynucleotide selected from the group consisting of

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(a) the polynucleotides listed in Tables 3, 4 and 6;

(b) polynucleotides having sequences that differ from the polynucleotides in (a), without changing the polypeptide encoded thereby; and

(c) polynucleotides which are at least 70% homologous to the polynucleotides of (a).

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10. An isolated polynucleotide which comprises a polynucleotide
selected from the group consisting essentially of:

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- (a) the polynucleotides listed in Tables 3, 4 and 6;
- (b) polynucleotides having sequences that differ from the polynucleotides in (a), without changing the polypeptide encoded thereby; and
- (c) polynucleotides which are at least 70% homologous to the polynucleotides of (a).

11. The polynucleotide according to claim 10, wherein the polynucleotide comprises a polynucleotide having at least 30, preferably at least 40, nucleotides from the polynucleotides of (a).

12. An isolated polynucleotide which comprises a polynucleotide selected from the group consisting of the polynucleotides listed in Tables 4 and 6.

13. A composition comprising the isolated polynucleotide according to claim 12.

14. An isolated polypeptide encoded by a polynucleotide, wherein the polynucleotide comprises a polynucleotide selected from the group consisting of:

- (a) the polynucleotides listed in Tables 3, 4 and 6;
- (b) polynucleotides having sequences that differ from the polynucleotides in (a), without changing the polypeptide encoded thereby; and

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(c) polynucleotides which are at least 70% homologous to the polynucleotides of (a).

15. The polypeptide according to claim 14, wherein the polypeptide is a portion which retains the biological activity thereof or a polypeptide which is at least substantially homologous or identical thereto.

16. The polypeptide according to claim 14, wherein the polypeptide is a dominant negative peptide which competes with the biological activity of the polypeptide.

17. An antibody which binds to a unique epitope of the polypeptide according to claim 14.

18. A method of diagnosing bladder cancer in a patient which comprises the step of:

determining, in a sample from the patient, the level of expression of at least one polypeptide, wherein a higher level of polypeptide compared to the level of the polypeptide in a patient free of bladder cancer is indicative of bladder cancer, by using the antibody of claim 17.

19. The method according to claim 18, wherein said determining step includes determining the presence of more than one polypeptide is detected by using more than one said antibody.

20. A method of treating bladder cancer-associated pathology in a subject by administering to the subject a therapeutically effective amount of a

chemical compound which inhibits a gene , or polypeptide encoded thereby, which comprises a polynucleotide selected from the group consisting of:

5 (a) the polynucleotides listed in Tables 3, 4 and 6;

10 (b) polynucleotides having sequences that differ from the polynucleotides in (a), without changing the polypeptide encoded thereby; and

15 (c) polynucleotides which are at least 70% homologous to the polynucleotides of (a).

20 21. A gene therapy vehicle for delivering a polynucleotide according to claim 11 to a subject, whereby the polynucleotide is expressed in the target cells of the subject.

25 22. An isolated antisense oligonucleotide complementary to a unique sequence within the polynucleotide according to claim 10.

30 23. An isolated antisense oligonucleotide complementary to the polynucleotide according to claim 11.

35 *Sub C5* 24. The method according to claims 1 and claims 18, wherein the bladder cancer is transitional cell carcinoma.

40 25. The method according to claim 18, wherein the bladder cancer is transitional cell carcinoma.

Add C6